UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

THE UNITED STATES OF AMERICA *et al.* *ex rel.* JULIE LONG, Plaintiffs, v. JANSSEN BIOTECH, INC., Defendant.	Civil Action No. 16-CV-12182-FDS

PLAINTIFF'S MEMORANDUM OF LAW IN SUPPORT OF MOTION TO COMPEL THE PRODUCTION OF DOCUMENTS AND A COMPLETE AND PROPER PRIVILEGE LOG

TABLE OF CONTENTS

Plaintiff-relator Julie Long submits this memorandum of law in support of her motion under Federal Rule of Civil Procedure 37(a) and Local Rule 37.1 requesting the Court to order defendant Janssen Biotech, Inc., to produce the following discovery within ten days:

A. A complete privilege log identifying all documents withheld under a claim of privilege and providing sufficient detail to enable Plaintiff to assess the propriety of the privilege asserted;

B. Requested documents that are in the possession of current and former employees known to have discoverable information;

C. Documents responsive to Requests for Production 8 and 21-27 located in its corporate files and possessed by current and former employees known to have discoverable information;

D. All documents responsive to Requests for Production 4, 6, 7, 16, 31 and 34; and

E. All relevant documents in Karen Trahan's and Plaintiff's electronic files that pre-date October 28, 2006.

This motion is necessary because Janssen is disregarding its discovery obligations and the Court's directives and acting as though it is allowed to pick and choose the discovery it provides.

Plaintiff attempted in good faith to resolve these discovery disputes before seeking the Court's intervention. Plaintiff set forth the issues raised herein in correspondence to Janssen's counsel and initiated a telephone conference to review the issues. The correspondence Plaintiff sent to Janssen is attached as Exhibits 1 and 2. The conference, which took place on November 17 and was attended by attorneys Leopold, Preston, and Martin on behalf of Plaintiff and attorneys Posner, Grigsby, Tremont, and Cobb on behalf of Janssen, lasted approximately 30 minutes. Janssen's counsel addressed some of Plaintiff's questions concerning the privilege log but refused to engage in any discussion or attempt to resolve the issues raised in this motion.

I. FACTUAL BACKGROUND

Starting in approximately 2001, one of Janssen's main strategies for growing sales of Remicade and Simponi ARIA—two drugs administered via infusion—was to promote the

infusion business model by helping rheumatology and gastroenterology practices open in-office infusion suites ("IOI") and, after an IOI was open, by influencing the physician practices to perform more infusion procedures. As part of this strategy, Janssen employed a large team of medical practice advisers to furnish free, ongoing operational support to physicians who were committed to the infusion business model and opened IOIs. Janssen called this special team of employees "Area Business Specialists," or "ABSs" for short. Janssen also paid business consultants with expertise in medical practice and infusion business management, such as Xcenda and The Lash Group, to assist the physician practices with opening and operating IOIs.

Janssen had ABSs and outside consultants meet with physician practices that did not have an IOI and advise them to open an IOI to perform infusion procedures. If a physician practice was interested, Janssen then advised the practice on how to open and set up the IOI. Once open, Janssen wanted to make sure the IOIs remained open and that the physician practices grew the number of infusion procedures they performed in the IOIs. Janssen did all this to induce the physician practices to prescribe, purchase, and infuse more Remicade and Simponi ARIA.

The free practice management and infusion business advice and support that Janssen had ABSs and outside consultants regularly provide the physician practices covered a wide range of topics that fell within four general categories: (1) opening, designing, and setting-up an IOI; (2) growing the IOI and improving the IOI's efficiency and optimizing its infusion schedule; (3) managing the IOI business; and (4) managing relationships with insurance companies and negotiating higher reimbursement rates for regularly billed services and drugs. Janssen often referred to the practice management and infusion operations advice and support and the presentations it utilized in providing the advice and support as, among other things, "presentations" and "programs." These free business services and the related presentations and

programs are collectively referred to herein as "IOI Support."

The IOI Support, which helped physicians open, operate, manage, and grow IOIs, where they infused a variety of infusible drugs, not just Remicade and Simponi ARIA, provided broad value to the physicians. Although the IOI Support applied to the overall infusion business and all infusible drugs, Janssen's purpose in providing these services for free was to gain loyalty and induce sales and infusions of its products (Remicade and Simponi ARIA).

Plaintiff alleges that by providing the various types of valuable IOI Support to induce the physicians to prescribe and administer Remicade and Simponi ARIA infusions to their patients, many of whom are covered by Medicare, Janssen violated the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b. Plaintiff also alleges that by providing the valuable IOI Support Janssen corrupted and tainted the recipients' treatment decisions and, accordingly, rendered the bills those physicians submitted to Medicare for Remicade and Simponi ARIA and the related infusion procedures false and ineligible for reimbursement. By providing illegal remuneration that resulted in the submission of false claims to Medicare, Janssen violated the False Claims Act ("FCA"), 31 U.S.C. § 3729, *et seq*. *See* 42 U.S.C. § 1320a-7b(g).

II. PROCEDURAL BACKGROUND

A. The Case Is In The Second Stage Of Discovery Where Plaintiff Can Obtain Full Discovery Concerning All Issues With The Exception Of Field-Level Activities In Other Regions And Afterwards The Court Will Evaluate The Evidence By Undertaking A Bellwether Summary Judgment Process

Discovery was initially focused on documents and information relevant to confirming that the IOI Support was in fact provided in Plaintiff's former territory and that it was provided as part of a national strategy. The Court also used the first stage to assess how future discovery could be conducted in the most efficient manner. On October 22, the Court provided instructions regarding the second stage of the Court's case management plan. As part of this second stage, the

Court created a pre-trial bellwether summary judgment process through which it will evaluate whether the evidence sufficiently supports Plaintiff's allegations that Janssen's provision of the IOI Support violated the AKS and FCA. The pre-trial bellwether will be focused on the IOI Support Janssen provided to physician practices in Plaintiff's former territory of Central Pennsylvania. Under the plan, the bellwether summary judgment review will take place after the parties have completed discovery concerning all elements of Plaintiff's claims and Janssen's defenses. *See* Oct. 22, 2021 Status Conf. Tr. at (ECF No.203) at 11:5-12:10.

While making it clear that Plaintiff can obtain discovery of all aspects of the alleged kickback scheme—from discovery of what was happening in the field in Central Pennsylvania to discovery of Janssen's most senior management's knowledge and involvement in the alleged scheme—the Court maintained a regional limitation on field-level discovery during the second stage. For purposes of this stage, the Court believes it is unnecessary for Plaintiff to obtain discovery concerning specific details of what ABSs and physicians in other regions were doing because the bellwether will focus on how Janssen caused physicians in Central Pennsylvania to submit false bills to Medicare for Remicade and Simponi ARIA.

B. In Deciding Plaintiff's August 8, 2021 Motion To Compel, The Court Ordered Janssen To Produce A Privilege Log And Provide Plaintiff Written Confirmation Of The Status Of Its Document Production

Because of Janssen's substantial delay in producing most of the documents stored in its corporate files and databases that Plaintiff requested in her first and second sets of document requests served in December 2020 and January 2021, Plaintiff filed a motion to compel the production of these documents on August 6, 2021 (ECF Nos. 159-160). The documents Plaintiff moved to compel were collectively referred to in the motion as the "Corporate Documents."

After hearing argument on the motion on October 18, the Court ordered Janssen to

produce "all materials concerning the development of the programs, including, but not limited to: (1) the request for approval that was submitted to management and the Promotional Review Committee ("PRC"); and (2) management's and the PRC's analyses and discussions concerning such requests." *See* Oct. 18, 2021 Order (ECF No.194). With regard to the other categories of requested Corporate Documents addressed in the motion, the Court ordered the parties to confer about the status of the production and apprise the Court concerning the remaining differences. *See id.* In addition, the Court ordered Janssen to produce its privilege log by October 31. *See id.*

The Court subsequently held a status conference concerning the parties' status reports on October 28. The Court ordered Janssen to provide Plaintiff written confirmation concerning the status of outstanding discovery by October 31. *See* Oct. 28, 2021 Order (ECF No.205).

This motion to compel addresses the deficiencies in Janssen's document production as well as Janssen's incomplete and non-compliant privilege log. Janssen's privilege log is attached as Exhibit 3, and the letter Janssen provided concerning the status of its document production is attached as Exhibit 4. The issues raised herein are separate from the issues Plaintiff raised in the motion for reconsideration of discovery rulings filed on November 26 (ECF No.218).

III. ARGUMENT

A. Janssen Must Be Required To Log *All* Documents Being Withheld On The Ground Of Privilege And Its Privilege Log Must Comply With Rule 26(b)(5)(A) By Providing Adequate Descriptions Of The Withheld Documents

Janssen's privilege log (Ex. 3) does not identify *all* the documents Janssen is withholding on the ground of privilege and it fails to comply with Rule 26(b)(5)(A) because it does not provide Plaintiff with sufficient information to assess Janssen's privilege claims. The Court should direct Janssen to provide Plaintiff with a complete and sufficiently descriptive log.

"A party that withholds otherwise responsive documents under a claim of privilege must

expressly assert the privilege claimed and produce a privilege log that describes 'the nature of the documents, communications, or tangible things not produced or disclosed' and provides enough information for 'other parties to assess the claim.'" *Echavarria v. Roach*, 16-CV-11118-ADB, 2018 WL 6788525, at *2 (D. Mass. Dec. 26, 2018) (quoting Fed. R. Civ. P. 26(b)(5)(A)).[1] "'The party who invokes the privilege bears the burden of establishing that it applies to the communications at issue and that the privilege has not been waived.'" *Id*. (quoting *In re Keeper of Records (Grand Jury Subpoena Addressed to XYZ Corp.)*, 348 F.3d 16, 22 (1st Cir. 2003) (citation omitted)). "'Privilege logs do not need to be precise to the point of pedantry,' but 'a party who asserts a claim of privilege' is required 'to do the best that he reasonably can to describe the materials to which his claim adheres.'" *Id*. (quoting *In re Grand Jury Subpoena*, 274 F.3d 563, 576 (1st Cir. 2001)).

Janssen has not logged all withheld documents as required, nor has it done the best it reasonably could to describe the materials it is withholding under the claim of privilege, making it impossible for Plaintiff to assess whether such documents are, in fact, entitled to protection.

1. Janssen's Failure To Log All Withheld Documents

Janssen does not list all the documents it is withholding on the basis of privilege on its privilege log. For instance, Janssen has withheld from production documents in the custody of Freddy Jimenez, but it has failed to list these withheld documents on its log, depriving Plaintiff of the opportunity to consider and challenge Janssen's privilege claims as to these documents. Moreover, by omitting withheld legal advice and evaluations from its log, Janssen is concealing

[1] Because the federal questions raised by Plaintiff give rise to the Court's jurisdiction in this case, federal common law applies to the privilege issues. *See Gallardo v. Bd. of County Com'rs*, 881 F. Supp. 525, 529 (D. Kan. 1995) ("in a federal question case the court must apply federal common law, rather than state law, regarding evidentiary privileges") (citing Fed. R. Evid. 501; *E.E.O.C. v. Illinois Dep't of Employment Security*, 995 F.2d 106 (7th Cir. 1993)).

from Plaintiff relevant information about whether it sought legal advice or evaluated the lawfulness of providing the IOI Support. This information is highly relevant to, among other issues, how, if it all, Janssen assessed the legality of providing the IOI Support and whether Janssen knew that providing the IOI Support was unlawful. Indeed, the Court ordered Janssen to produce its evaluations concerning the legality of providing the IOI Support. *See* Apr. 23, 2021 Order (ECF No.120). Janssen must either produce the legal evaluations or identify them on its privilege log; it cannot entirely conceal their existence, as it is presently doing. *See* Fed. R. Civ. P. 26(b)(5); Local Rule 34.1(e); Protective Order - Ex. B (ECF No.98-1) at I.B.

Janssen must be required to identify all withheld documents on its privilege log.

2. Janssen's Failure To Provide Sufficient Information To Enable Plaintiff To Assess Its Claims Of Attorney-Client Privilege

Not every communication with or to an attorney is protected by the attorney-client privilege. "The privilege protects only those communications that are confidential and are made for the purpose of seeking or receiving legal advice." *In re Intuniv Antitrust Litig.*, 16-CV-12396-ADB, 2018 WL 6492747, at *2 (D. Mass. Dec. 10, 2018) (citing *XYZ Corp.*, 348 F.3d at 22). "These requirements apply with equal force to in-house attorneys, whose legal advice based on communications with corporate officers is protected, but whose general business advice is not." *Lynx Sys. Developers, Inc. v. Zebra Enter. Sols. Corp.*, CV 15-12297-GAO, 2018 WL 1532614, at *2 (D. Mass. Mar. 28, 2018) (citing *Texaco P. R., Inc. v. Dep't of Consumer Affairs*, 60 F.3d 867, 884 (1st Cir. 1995); *Neelon v. Krueger*, No. 12-cv-11198-IT, 2015 WL 4254017, at *4 (D. Mass. July 14, 2015)). Privileged communications become discoverable if the privilege is waived by subsequent disclosure to a third party. *See id*. The party asserting the privilege "bears the burden of establishing not only that the privilege applies to the communications at issue, but also that the privilege has not been waived." *Id*. at *3 (citing *XYZ Corp.* at 22).

Even a cursory review of Janssen's privilege log demonstrates that it has not met its burden of demonstrating the attorney-client privilege applies to the documents withheld on that basis. Janssen wholly disregards Federal Rule of Civil Procedure 26(b)(5)(A)(ii)'s specificity requirement and the Protective Order's similar requirement that the privilege log "contain[] information sufficient to enable the opposing party to assess the applicability of the privilege." *See* Protective Order - Ex. B (ECF No.98-1) at I.B.

Janssen uses basically the same description for all documents withheld on the ground of attorney-client privilege without providing any fact-specific information for each document that would enable Plaintiff to assess whether Janssen has properly invoked the privilege. *See* Ex. 3 at column titled "Purpose and Subject of Communication." Many entries contain no descriptions at all. *See, e.g.*, Ex. 3 at JANSSENBIO-PL-000003; JANSSENBIO-PL-000005; JANSSENBIO-PL-000013; JANSSENBIO-PL-000014; JANSSENBIO-PL-000015; JANSSENBIO-PL-000018. During the parties' meet and confer, Janssen explained that the documents without a description are child documents (*i.e.*, attachments) and the log should be read as applying the same description to these documents that Janssen gave to the parent documents. This explanation is insufficient, however, as all child documents/attachments will not necessarily be privileged, even if attached to a communication that is privileged. *See In re Intuniv Antitrust Litig.*, 16-CV-12396-ADB, 2018 WL 6492747, at *6 (D. Mass. Dec. 10, 2018) ("[D]ocuments do not become privileged simply because they are requested by or sent to an attorney in connection with litigation.") (citing *Pacamor Bearings, Inc. v. Minebea Co., Ltd.*, 918 F. Supp. 491, 511 (D.N.H. 1996) ("'Attachments which do not, by their content, fall within the realm of the privilege cannot become privileged by merely attaching them to a communication with the attorney.'")).

Janssen also appears to apply the attorney-client privilege to protect general discussions

among employees, rather than just those confidential communications "made for the purpose of seeking or receiving legal advice." *In re Intuniv Antitrust Litig.* at *2. For instance, entry JANSSENBIO-PL-000046 is an e-mail communication withheld under the attorney-client privilege, but the communication was not written by or received by an attorney—or even copied to an attorney. Yet, Janssen's description of the withheld communications is: "Email Chain requesting legal advice regarding preparation/review of internal training or internal guidance concerning practice management or IOI support." Janssen should be required to provide more detail to support its claim of privilege.

Privilege log entry JANSSENBIO-PL-000046 demonstrates another insufficiency. The participants in that communication are listed as Michael Schoeck, Elizabeth Lawless, and Greg Fenner—none of whom are identified as attorneys. Janssen does not provide any information regarding these individuals—or any of the individuals on the log other than those designated as attorneys—making it impossible for Plaintiff to analyze whether Janssen may have waived any purported privilege by including third parties in those communications. *See XYZ Corp.* at 22 ("When otherwise privileged communications are disclosed to a third party, the disclosure destroys the confidentiality upon which the privilege is premised.") (citing 2 Paul R. Rice, Attorney-Client Privilege in the U.S. § 9:79, at 357 (2d ed. 1999)). Nor can Plaintiff analyze whether Janssen may have waived any privilege by including employees without a need to know in the communications. *See Davine v. Golub Corp.*, CV 3:14-30136-MGM, 2017 WL 517749, at *2 (D. Mass. Feb. 8, 2017) (communications among corporate employees "'that discuss or relay counsel's legal advice ... are privileged to the extent that the employees are in a 'need to know' position or bear some responsibility for the subject matter underlying the consultation.'") (quoting *In re Prograf Antitrust Litig.*, No. 1:11-md-02242-RWZ, 2013 WL 1868227, at *2 (D.

Mass. May 3, 2013)).

Janssen must be compelled to produce a privilege log that identifies in detail the facts regarding the documents being withheld so that Plaintiff has the information necessary to assess the propriety of the claimed privilege.

3. Janssen's Failure To Provide Sufficient Information To Enable Plaintiff To Assess Claims Of Work Product Privilege

Janssen has indicated in its privilege log that it is withholding documents as privileged work product when such documents were prepared long before Plaintiff filed this lawsuit. *See, e.g.,* Ex. 3 at JANSSENBIO-PL-00006 and JANSSENBIO-PL-00007 (asserting work product with regard to a presentation and spreadsheet dated August 31, 2007); JANSSENBIO-PL-00008 and JANSSENBIO-PL-00009 (claiming work product with regard to presentations from December 2010). As these materials were obviously not prepared in anticipation of this litigation, and Janssen has failed to reveal any details regarding what, if any, litigation the materials were prepared in anticipation of, Janssen has failed to provide sufficient information on its privilege log for Plaintiff to assess the viability of its work product privilege claims.

"The work product doctrine, first recognized by the Supreme Court in *Hickman v. Taylor*, 329 U.S. 495 (1947), and partially codified in Federal Rule of Civil Procedure 23(b)(3), 'protects against disclosure of materials that a party, her attorney, or her representative prepares in anticipation of litigation.'" *Davine v. Golub Corp.*, CV 3:14-30136-MGM, 2017 WL 517749, at *3 (D. Mass. Feb. 8, 2017) (quoting *Columbia Data Products, Inc. v. Autonomy Corp. Ltd.*, CIV.A. 11-12077-NMG, 2012 WL 6212898, at *11 (D. Mass. Dec. 12, 2012)). The doctrine creates a zone of privacy allowing a party and their attorney to prepare for litigation without fear of intrusion from their adversaries. *See id*. (citing *In re Grand Jury Subpoena*, 220 F.R.D. 130, 141 (D. Mass. 2004)). "The First Circuit requires a close connection between the information for

which work product protection is sought and litigation for which the information is procured." *Id*. "[D]ocuments that are prepared to aid a corporation with its compliance obligations, rather than because of pending or imminent litigation, are not protected by the work product doctrine." *Id*. (citing *Lewis v. Wells Fargo & Co.*, 266 F.R.D. 433, 439 (N.D. Cal. 2010)).

Courts have rejected a claim of work product privilege where a significant amount of time passed between the creation of the information and the litigation in which the information was requested. *See Davine* at *4 (four-year lapse between purported work product and litigation defeated any claim that documents were created in anticipation of instant litigation); *Securities Exch. Comm'n v. Navellier & Assocs.*, 2018 WL 6727057 at *4 (D. Mass. 2018) (two-year time lapse between dates of documents sought and government investigation did not make prospect of litigation anticipated). Plaintiff expects that to be the case here, but first Janssen must provide a log that specifies the litigation for which the requested information was prepared so that Plaintiff is able to analyze the legitimacy of Janssen's work product privilege claims.

B. Janssen Must Be Required To Collect And Produce Requested Documents Held by Non-Custodians

It is the "duty of the party who has possession, custody, or control of ESI that is relevant to the claims and defenses in the case to take reasonable steps to preserve ESI that is within the scope of discovery." The Sedona Principles, 3d Ed.: Best Practices, Recommendations & Principles for Addressing Electronic Document Production, 19 Sedona Conf. J. 1, 118-19 (2018) (citing Principle 5, footnote omitted). "Those discovery obligations also include the duty to use reasonable efforts to locate and produce ESI responsive to the opposing party's requests and within the scope of discovery." *Id*. "To enforce these responsibilities, the attorney's signature on a discovery response 'certifies that the lawyer has made a reasonable effort to assure that the client has provided all the information . . . responsive to the discovery demand' and has made

'reasonable inquiry into the factual basis of his response.'" *Id*. (quoting 1983 Advisory Comm. Note to Rule 26(g)).

In a large case like this one where there will be a significant amount of document production, there are two ways that documents possessed by current and former employees should be produced. First, under the Federal Rules, the company is obligated to collect and produce all non-privileged, responsive documents from the files of current and former employees known to have discoverable information (the "Employee Document Production"). Second, under the parties' ESI Protocol, the company must produce documents responsive to the agreed upon search queries conducted of the electronic files of custodians selected by the parties (the "Custodian Production").

Janssen has refused to comply with its obligation to make an Employee Document Production. It has refused to identify the current and former employees most likely to have significant discoverable information and has likewise refused to search for or produce responsive information held by those individuals. Instead, Janssen has limited its production of records possessed by current and former employees to the Custodian Production. But even this production is highly inadequate. Janssen has limited the number of custodians to an extremely small number, initially agreeing only to produce documents from Plaintiff's own electronic files, the files of three direct supervisors, and the files of one Regional Business Director. Ultimately, during the first phase, Janssen performed the search queries and produced some of the relevant electronic files for just 12 employees and Plaintiff. To obtain important discoverable information that Janssen has refused to produce by failing to make an Employee Document Production and severely limiting the Custodian Production, Plaintiff has separately requested that the Court order that several more employees be added as custodians.[2] But Plaintiff should not be forced to

[2] Because the case is no longer in the first stage and the Court now wants discovery on all issues completed, as part of her motion for reconsideration, Plaintiff requested that the Court reconsider the July

seek Court intervention to make Janssen comply with its discovery obligations.

The result of Janssen's conduct is that it has not lived up to its discovery obligations because it has limited its search and production of documents to just a limited number of custodians, while improperly concealing responsive and highly relevant evidence held by current and former employees known to have discoverable information. Janssen has not made a single Employee Document Production despite knowing that employees possess discoverable information. By excluding and concealing this relevant evidence, Janssen is flouting its discovery obligations and significantly impeding the discovery process.

The Court should order Janssen to comply with its basic discovery obligation of collecting and producing requested documents possessed by current and former employees who had significant involvement in the IOI Support strategy and scheme.

C. For Several Document Requests, Janssen Did Not Collect Responsive Documents From Its Corporate Repositories Or Employees Who It Knows Had Significant Involvement

In Plaintiff's first set of requests for production served last December (a copy is attached as Exhibit 5), plaintiff included the following requests for production ("RFP"):

- RFP 8: Management-Level Documents sufficient to show the factors or criteria that determined how frequently IOI Accounts (including the Phase 1 Accounts) received IOI Support.
- RFP 21: All Management-Level Documents concerning the returns or benefits that you derived from providing the IOI Support.
- RFP 22: All Management-Level Documents concerning the benefits or value that IOI Accounts derived from the IOI Support.
- RFP 23: All Management-Level Documents concerning the answers, results, and findings from surveys and market research concerning the benefits or value that IOI Accounts derived from the IOI Support.
- RFP 24: All Management-Level Documents concerning the purpose, reason, or objective of

26, 2021 ruling denying Plaintiff's request to add more employees as custodians. *See* Plf.'s Mem. of Law in Support of Omnibus Mtn. for Reconsideration of Discovery Rulings at Part III.A.

providing the IOI Support.

- RFP 25: All Management-Level Documents concerning the use of the IOI Support to:
  (a) Grow or maintain Remicade and/or Simponi ARIA utilization or sales;
  (b) Cause or influence physicians to commit to or increase their confidence in the infusion business model or Remicade business model.

- RFP 26: All Management-Level Documents concerning the influence, effect, or impact that providing IOI Support had on IOI Accounts' utilization of Remicade or Simponi ARIA.

- RFP 27: All Management-Level Documents concerning the ability to effect change in IOI Accounts or influence IOI Accounts to perform more Remicade and/or Simponi ARIA infusions through Managing Biologics in the Physician Office (MBPO), Account Review, IBiz, Infusion Optimization Modeler (IOM), and/or Infusion Services Review (ISR) consultative sessions.

In its November 1 letter reporting on the status of its production of documents responsive to these and other document requests, Janssen indicated that it has satisfied its obligation to produce documents responsive to these requests for production because the ESI searches of the 12 custodians' and Plaintiff's documents captured some documents that were responsive to these document requests. *See* Ex. 4. Thus Janssen never searched for documents responsive to these requests that are located its corporate repositories and files and that are located in the files of employees who it knows had significant involvement in the promotional strategy and scheme at issue. It has taken no steps to collect and produce the documents requested in RFP 8 and RFPs 21 through 27 from any source other than the 12 custodians and Plaintiff.

Performing ESI searches of a small number of custodians electronic files does not satisfy Janssen's obligation to collect and produce requested evidence that exists in its corporate files and that is possessed by employees who it knows had significant involvement in the development, approval, review, and/or oversight of Janssen's provision of the IOI Support.

Janssen must be ordered to produce the documents responsive to these requests that are located in the companies files as well as in the files of its employees who it knows had significant involvement in the development, approval, review, and/or oversight of Janssen's

provision of the alleged kickbacks.

D. For Requests For Production 4, 6, 7, 16, 31 & 34, Janssen Should Be Required To Produce All Responsive Documents

1. Janssen's Relevant Compliance Policies & Guidance

In RFP 34, Plaintiff requested that Janssen produce:

> All documents concerning guidance and policies related to providing services or support to physicians, including the "Guidance Document on Consulting and/or Services Provided to Customers," "Guidance Document on Free Goods and Services," and "Guidance Documents on Education Support."

Janssen has produced some, but not all, of the requested compliance guidance and policies. It has only produced policy documents for a limited number of years, and it has not produced several guidance documents that are referenced in policy documents that it did produce. For example, it has not produced the guidance documents titled: "Guidance on Consulting and Product-Related Services Provided to Customers" (a/k/a "Guidance Document on Consulting and/or Services Provided to Customers"; "Guidance Document on Consulting and Product-Related Items and Services Provided to Customers"); "Guidance Document on Free Goods and Services"; and "Guidance Document on Educational Support." Nor has Janssen produced any of its analyses of whether providing the IOI Support complied with the guidance and policies.

Janssen must be required to produce all relevant compliance policies and guidance, including those that pre-date October 2006. In addition, the company must produce any analyses concerning whether providing the IOI Support complied with the guidance and policies.

2. Reports That Tracked Critical Information About The Bellwether Accounts

In RFP 16, Plaintiff requested that Janssen produce:

> All documents that show or track the following information for any and all of the Phase 1 Accounts:
> (a) Whether you assisted the account with opening the IOI;
> (b) When the account opened its IOI;

(c) If applicable, when the account closed its IOI;
(d) Each occasion an ABS or Outside Consultant called on or visited the account;
(e) Each occasion an ABS or Outside Consultant provided a dinner or lunch program;
(f) Each occasion an ABS or Outside Consultant provided any IOI Support;
(g) Each occasion an ABS provided a Managing Biologics in the Physician Office (MBPO), Account Review, IBiz, Infusion Optimization Modeler (IOM), and/or Infusion Services Review (ISR) consultative session;
(h) Remicade and Simponi ARIA utilization volume;
(i) Utilization volume of Competing Drugs (collectively or individually);
(j) Each occasion the account committed to the ABS that it would prescribe Remicade and/or Simponi ARIA to additional patients;
(k) Each occasion the account committed to the ABS that it would increase infusion capacity or volume;
(l) The number of Medicare patients prescribed Remicade, Simponi ARIA, or a competing drug or biologic;
(m) Claims for reimbursement submitted to Medicare (including Medicare Advantage) for Remicade or Simponi ARIA and related infusion procedures;
(n) Payer mix.

In its November 1 letter, Janssen reported that that it "produced data from CRM systems … of contacts between the Phase 1 Accounts and Julie Long or Dana Griffith between October 28, 2006, and February 19, 2016." Ex. 4. However, that is only one of the multiple items requested in RFP 16. For instance, Janssen has not provided information showing when the accounts opened its IOI or each occasion an Outside Consultant provided IOI Support to the physician practices. Nor has Janssen provided the records it used to monitor how many patients at each account were insured by Medicare.

In addition, Plaintiff must be able to determine when Janssen began providing the IOI Support in the bellwether territory (through Plaintiff and other ABSs).

Janssen must be required to produce documents reporting the information requested in all subcategories of RFP 16. And the beginning date for these productions must be the date when Janssen began providing the IOI Support to the physician practices in Central Pennsylvania.

3. Janssen's Communications With The Government

Plaintiff is entitled to know what information Janssen disclosed to U.S. Department of Justice concerning this action. Plaintiff is also entitled to know whether Janssen ever sought guidance or an advisory opinion from HHS-OIG. In addition, as one of its asserted defenses, Janssen alleges that Medicare knew Janssen was providing the alleged kickbacks but decided to pay the false claims related to Remicade and Simponi ARIA anyway. As a result, in RFP 31, Plaintiff requested:

> All documents concerning communications with, or statements made by or to, any federal or state government agency about providing free services or product support to physicians.

The only communications Janssen has produced are cover letters related to its production of the documents that the Department of Justice requested in its Civil Investigation Demand.

Because Janssen has asserted a materiality defense, it should be required to produce any communications it had with Medicare concerning its provision of the IOI Support to physician practices. Janssen should also be required to produce all communications it had with the Department of Justice concerning this action and all its communications with HHS-OIG concerning any requests for guidance or an advisory opinion related to the IOI Support. Recognizing the relevance of Janssen's communications with the Department of Justice regarding its investigation as well as the relevance of any communications Janssen may have had with HHS-OIG to seek guidance or an advisory opinion concerning the IOI Support, the Court denied Janssen's motion for a protective order concerning these communications. *See* Dec. 1, 201 Order (ECF No. 221).[3]

[3] It should be noted that Janssen requested that Plaintiff produce all of her and her counsel's communications with the United States. Even though Plaintiff provided the requested documents and a privilege log listing the documents withheld due to privilege, Janssen has refused to produce all its communications with the United States, none of which are privileged.

4. Job Descriptions For Positions That Had Significant Involvement In The IOI Support Strategy And Scheme

In RFP 4, Plaintiff requested that Janssen produce:

> Management-Level Documents sufficient to show the responsibilities of the following positions (or their equivalents) related to the promotion or support of Remicade and Simponi ARIA: ABS, Regional Business Manager, Regional Business Director, Regional Business Coordinator, Remicade Product Manager, Remicade Product Director, Infusion Group Product Director, Business Development Manager, Vice President Immunology Sales, Director of Marketing Immunology, Immunology Sales Specialist, and Medical Science Liaison.

Janssen produced documents setting forth the job descriptions for some positions, such as ABSs and Regional Business Managers, in which the employees had significant involvement in the strategy and scheme at issue. But even for these positions, Janssen provided its job descriptions for only select years. The job descriptions for all positions where the employees had significant responsibility for the development, review, approval, delivery, or oversight of the IOI Support are highly relevant because the job descriptions summarize witnesses' specific roles concerning the IOI Support. This discrete group of core documents is proportionate to the needs of the case.

Janssen must be required to produce all versions of the requested job descriptions, including those pre-dating October 2006.

5. Janssen's Contracts With Outside Consultants To Develop And/Or Provide IOI Support To Select Physician Practices

In RFP 7, Plaintiff requested that Janssen produce:

> All contracts or agreements between you and any Outside Consultant related to: (a) providing advice or information to IOI Accounts; or (b) creation of presentations or programming utilized by ABSs in connection with providing IOI Support.

Janssen has only produced some of it contracts with certain outside consultants to develop and/or provide the IOI Support. Here again, Janssen must produce all the requested contracts. These contracts are important because they contain descriptions of the IOI Support Janssen paid the

outside health care consultants to develop and/or provide to physician practices, including those in Central Pennsylvania. Moreover, Janssen is withholding contracts that pre-date October 2006 even though these contracts are highly relevant and constitute important foundational evidence regarding the development of the IOI Support, the nature of the IOI Support provided, the value of the IOI Support, and Janssen's intent in providing the IOI Support.

Janssen must be required to produce all contracts with outside consultants to develop and/or provide the IOI Support, including those that pre-date October 2006.

6. Janssen's Document Retention And Preservation Policies

In RFP 6, Plaintiff requested that Janssen produce:

> All documents concerning your policies and practices regarding document retention, document destruction, records management, disaster recovery, and litigation holds.

Janssen limited its production to its current document retention policy. Although the current policy is relevant, the policies that were in place at the time Janssen learned of this litigation are far more relevant. In addition, Janssen's documents concerning its preservation of the documents that are relevant to this lawsuit must be produced.

E. Janssen Should Be Required To Produce All Relevant Documents In Karen Trahan's And Plaintiff's Electronic Files That Pre-Date October 2006

It has become clear that Karen Trahan is one of the important witnesses in this case. Ms. Trahan served as a Regional Business Director responsible for the Eastern United States, including Central Pennsylvania, from approximately 2000 to 2015. In this capacity, Ms. Trahan had substantial involvement in the development and oversight of the IOI Support Janssen provided to physician practices in Central Pennsylvania. Despite Ms. Trahan's central role in the development of the IOI Support services in the early 2000s, in performing search queries of this key witness's documents, Janssen excluded all documents from before October 28, 2006.

Similarly, in view of the Court's plan to conduct a bellwether summary judgment process focused on Central Pennsylvania, Janssen should not be allowed to withhold relevant documents from Plaintiff's files that pre-date October 28, 2006.

The documents from Ms. Trahan's and Plaintiff's electronic files that pre-date October 28, 2006 are critical to understanding the development of the various types of IOI Support Janssen provided to physician practices in Central Pennsylvania after October 2006. In addition, Ms. Trahan's and Ms. Long's documents the pre-date October 28, 2006 will provide important information concerning when, why, and how Janssen began providing the IOI Support to physician practices in the bellwether territory.

IV. CONCLUSION

For the foregoing reasons, the Court should order Janssen to, within 10 days, produce:

A. A complete privilege log identifying all documents withheld under a claim of privilege and providing sufficient detail to enable Plaintiff to assess the propriety of the privilege asserted;

B. Requested documents that are in the possession of current and former employees known to have discoverable information;

C. Documents responsive to Requests for Production 8 and 21-27 located in its corporate files and possessed by current and former employees known to have discoverable information;

D. All documents responsive to Requests for Production 4, 6, 7, 16, 31 and 34; and

E. All relevant documents in Karen Trahan's and Plaintiff's electronic files that pre-date October 28, 2006.

Plaintiff requests oral argument on this motion.

Dated: December 3, 2021

Respectfully submitted,

/s/ Theodore J. Leopold
Theodore J. Leopold (admitted pro hac vice)
Leslie M. Kroeger (admitted pro hac vice)
Diana L. Martin (admitted pro hac vice)
Poorad Razavi (admitted pro hac vice)
COHEN MILSTEIN SELLERS & TOLL PLLC
11780 U.S. Highway One, Suite N500
Palm Beach Gardens, FL 33408
(561) 515-1400
tleopold@cohenmilstein.com
lkroeger@cohenmilstein.com
dmartin@cohenmilstein.com
prazavi@cohenmilstein.com

Casey M. Preston (admitted pro hac vice)
Gary L. Azorsky (admitted pro hac vice)
Jeanne A. Markey (admitted pro hac vice)
COHEN MILSTEIN SELLERS & TOLL PLLC
1717 Arch Street, Suite 3610
Philadelphia, PA 19103
(267) 479-5700
cpreston@cohenmilstein.com
gazorsky@cohenmilstein.com
jmarkey@cohenmilstein.com

Jonathan Shapiro (BBO No. 454220)
SHAPIRO & TEITELBAUM LLP
90 Canal Street, Suite 120
Boston, MA 02116
(617) 742-5800
jshapiro@jsmtlegal.com

Counsel for Plaintiff Relator Julie Long

CERTIFICATE OF SERVICE

I hereby certify on this 3rd day of December, 2021, that this document filed through the CM/ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing.

/s/ Theodore J. Leopold
Theodore J. Leopold (admitted pro hac vice)